

Mesothelium Dental Membrane

JUL 11 2013

510(k) Summary

Submitted by: DSM Biomedical
735 Pennsylvania Drive
Exton, PA 19341 USA

Contact Person: Lori Burns, MS; RAC
Manager Regulatory Affairs
Ph: (484) 713-2186
Fax: (484) 713-2903

Date Prepared: July 2, 2013
510(K) #: K121310

Device:

Trade Name: Mesothelium Dental Membrane
Common/Usual Name: Resorbable Membrane for Guided Tissue and Bone Regeneration
Classification Name: Barrier, Animal Source, Dental
Proposed Classification: 21 CFR 872.3930, Class II, NPL

Device Description:

Mesothelium Dental Membrane is a barrier membrane for guided tissue and bone regeneration in dental applications. It is a resorbable porcine-mesothelium-derived extracellular matrix available as a lyophilized sheet. Mesothelium Dental Membrane is available in a variety of shapes and sizes. Furthermore, the device can be easily trimmed or shaped to the appropriate size to fit the defect to be treated. The device is packaged sterile in a double-layer package.

Intended Use:

Mesothelium Dental Membrane is indicated for:

- simultaneous use of GBR-membrane and implants.
- augmentation around implants placed in immediate extraction sockets.
- augmentation around implants placed in delayed extraction sockets.
- localized ridge augmentation for later implantation.
- alveolar ridge reconstruction for prosthetic treatment.
- filling of bone defects after root resection, cystectomy, removal of retained teeth.
- guided bone regeneration in dehiscence defects.
- guided tissue regeneration procedures in periodontal defects.

Predicate Devices:

Manufacturer	Device	510(k)
Ed. Geistlich Soehne Ag Fuer Chemische Industrie	K050446	Bio-Gide®
RTI Biologics	K073097	CopiOs™ Pericardium Membrane

Technological Characteristics:

The intended use, product design, material, function and target population of Mesothelium Dental Membranes are substantially equivalent to the FDA cleared and legally marketed predicate devices Bio-Gide (K050446) and CopiOs Pericardium Membrane (K073097).

Medical Device Name	Mesothelium Dental Membrane	Bio-Gide	CopiOs Pericardium Membrane
Origin	Porcine	Porcine	Bovine
Device Characteristics	<p>Extracellular matrix</p> <p>Cell-occlusive</p> <p>Implantable</p> <p>Resorbable</p>	<p>Extracellular Matrix</p> <p>Cell-occlusive</p> <p>Implantable</p> <p>Resorbable</p>	<p>Extracellular Matrix</p> <p>Cell-occlusive</p> <p>Implantable</p> <p>Resorbable</p>
Intended Use	<p>Mesothelium Dental Membrane is indicated for simultaneous use of GBR-membrane and implants; augmentation around implants placed in immediate extractions sockets, augmentation around implants placed in delayed extraction sockets, localized ridge augmentation for later implantation, alveolar ridge reconstruction for prosthetic treatment, filling of bone defects after root resection, cystectomy removal of retained teeth, guided bone regeneration in dehiscence defects, guided tissue regeneration procedures in periodontal defects.</p>	<p>Bio-Gide is indicated for simultaneous use of GBR-membrane and implants; augmentation around implants placed in immediate extractions sockets, augmentation around implants placed in delayed extraction sockets, localized ridge augmentation for later implantation, alveolar ridge reconstruction for prosthetic treatment, filling of bone defects after root resection, cystectomy removal of retained teeth, guided bone regeneration in dehiscence defects, guided tissue regeneration procedures in periodontal defects.</p>	<p>CopiOs is intended for use in oral surgical procedures as a resorbable material for augmentation around implants placed in immediate extraction sockets, augmentation around implants placed in delayed extraction sockets; localized ridge augmentation for later implantation; alveolar ridge reconstruction for prosthetic treatment; filling of bone defects after root resection, cystectomy, removal of retained teeth; guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.</p>
Biocompatibility	Yes	Yes	Yes
Non pyrogenic	Yes	Yes	Yes
Resorbable	Yes	Yes	Yes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – W066-G609
Silver Spring, MD 20993-0002

July 11, 2013

DSM Biomedical
C/O Ms. Lori Burns, MS, RAC
Manager, Regulatory Affairs
735 Pennsylvania Drive
EXTON PA 19341

Re: K121310
Trade/Device Name: Mesothelium Dental Membrane
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Code: NPL
Dated: July 2, 2013
Received: July 5, 2013

Dear Ms. Burns:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121310

Device Name: Mesothelium Dental Membrane

Indications for Use: Mesothelium Dental Membrane is indicated for: simultaneous use of GBR-membrane and implants, augmentation around implants placed in immediate extraction sockets, augmentation around implants placed in delayed extraction sockets, localized ridge augmentation for later implantation, alveolar ridge reconstruction for prosthetic treatment, filling of bone defects after root resection, cystectomy, removal of retained teeth, guided bone regeneration in dehiscence defects and guided tissue regeneration procedures in periodontal defects.

The device is intended for one time use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner, DDS, MA
Mary S. Runner -S
2013.07.11
11:29:45 -04'00'

Page of

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121310